

**FDA Convenes “Expert” Panel,
Ignoring EPI’s Response and All Letters**



Brain stimulation tech gets a date with the FDA

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The FDA sets a date to discuss a proposed rule requiring PMA review for cranial electrotherapy stimulators.

The FDA set a date in February for the public meeting on whether cranial electrotherapy stimulators need increased regulatory oversight.

The devices, heretofore cleared for the U.S. market via the 510(k) process, apply electrical currents to the brain through the skin for the treatment of anxiety, depression, insomnia and pain.



The watchdog agency's Neurological Devices Panel of the Medical Devices Advisory Committee will consider requiring pre-market approval review for CES devices on February 10, 2012, according to an [FDA notice](#).

CES device maker Alpha-Stim last month launched a campaign opposing the ruling.

"The economic impact of the ruling is to impose a process that the FDA estimates will cost the company \$1 million, for a product they approved over 30 years ago," the company wrote in a [press release](#). "Alpha-Stim and its supporters find the ruling overly aggressive and in complete opposition to all the positive information found in studies that Alpha-Stim diligently provided."

Alpha-Stim's CES technology is approved for over-the-counter sales in Europe, Canada and China, and the devices have survived six FDA reviews since 1981.

The pre-market approval ruling would cost the EPI Inc. subsidiary \$1 million for a product that the FDA approved more than 30 years ago, the company said.

More than 150 public submissions have been filed on the proposal to date.

"Cranial Electrotherapy Stimulation is critical to the health of many veterans, chronic pain and chronic disease patients who otherwise cannot tolerate pharmaceutical intervention," Nebraska physician Dr. Joyce Swanson wrote, urging the FDA to down-classify the devices to Class II. "Red tape means reduced access, increased reliance on medical intervention and increase medical costs for these patients."

The public meeting will take place February 10, 2012, at the Hilton Washington in Washington D.C. from 8:00 a.m. to 6:00 p.m.

<http://www.massdevice.com/news/brain-stimulation-tech-gets-date-with-fda>

